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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,660	01/18/2007	Max Aebi	001227.0210	6656
69695	7590	10/27/2010	EXAMINER	
STROOCK & STROOCK & LAVAN, LLP			WAGGLE, JR, LARRY E	
180 MAIDEN LANE			ART UNIT	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/539,660	AEBI ET AL.	
	<b>Examiner</b> Larry E. Waggle, Jr	Art Unit 3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 31 August 2010.  
 2a) This action is FINAL.      2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1 and 4-21 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1 and 4-21 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 14 June 2005 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/GS-6)  
 Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_  
 5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_

## DETAILED ACTION

### *Drawings*

The drawings are objected to because in Figures 1 and 2 central axis 2 and swivel axis 3 do not appear to be in the correct positional relationship with respect to swivel axis 4. It appears they should be shifted further back, along swivel axis 4, to be consistent with the disclosure (i.e. page 7, lines 17 and 18) stating that edge 53 forms swivel axis 3. It appears Figure 3 more accurately depicts the correct location of central axis 2. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Abstract***

The abstract of the disclosure is objected to because, in lines 11, 12 and 16, the terms "axle" and "axles" (3 instances) should read:

--"axis" and "axes"--

Correction is required in order to make the abstract consistent with the amendments to the claims due to the 35 U.S.C 112 2<sup>nd</sup> rejection, mailed 05 August 2010. See MPEP § 608.01(b).

***Specification***

The disclosure is objected to because of the following informalities:

On page 1, line 9 and page 3, line 3, the phrases "according to Patent Claim 22" and "comprising the steps of Claim 22" should be removed due to the cancelation of claim 22.

On page 3, lines 19, 20 and 31 (3 instance), the terms "axles" and "axle" should read:

--"axes" and "axis"--

On page 7, lines 1, 2, 3, 8, 12, 14, 16, 18 and 19 (10 instance), the term "axle" should read:

--"axis"--

These objections are in order to make the specification consistent with the amendments to the claims due to the 35 U.S.C 112 2<sup>nd</sup> rejection, mailed 05 August 2010.

Appropriate correction is required.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification is silent with respect to the terms "wedge member" and "pointed tip," as now required by amended claim 1. It appears the term "wedge member" is in reference to elevations 49 and 50 and the term "pointed tip" is in reference to edges 51 and 53. If this is the case, the specification should be amended to include these terms which appear have support in the Figures. No new matter should be entered.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 recites the limitation "the first joint section" in lines 2 and 3. There is insufficient antecedent basis for this limitation in the claim.

Claim 5 recites the limitations "the lower joint section" in line 2 and "the central joint section" in line 4. There is insufficient antecedent basis for this limitation in the claim. In order to be consistent with claim 1 and the specification, it appears these limitation should read:

--"the lower section" and "the central joint element"--

Claim 6 recites the limitations "the upper joint section" in line 2 and "the central joint section" in line 4. There is insufficient antecedent basis for this limitation in the claim. In order to be consistent with claim 1 and the specification, it appears these limitation should read:

--"the upper section" or "upper joint element" and "the central joint element"—

Consult the specification (page 7, lines 5-15) for clarity.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**Claims 1, 4-7** are rejected under 35 U.S.C. 103(a) as being unpatentable over Mitchell (US Patent 7,273,496) in view of Angeli (US Patent 5,593,447).

Mitchell discloses an intervertebral implant (100) having a central axis, an upper section (110) having a ventral side, a dorsal side, two lateral sides, a top apposition surface (112), and a bottom surface (116) and a lower section (120) having a ventral side, a dorsal side, two lateral sides, a top apposition surface (122), and a bottom surface (126), wherein the upper and lower sections (110 and 120) are moveable with respect to each other (column 3, lines 27-30) via two joints arranged between the two sections, the two joints each having an upper joint element (150) in the upper section (110), a central joint element (130), and a lower joint element (160) in the lower section (120) (i.e. the first joint is defined by the interaction between 150 (i.e. depression forming the upper joint element) and 210 (i.e. joint section defining a swivel axis with a wedge-like member (i.e. portion extending into and bearing against 150) having a rounded tip) and the second joint is defined by the interaction between 160 (i.e. depression forming the lower joint element) and 220 (i.e. joint section defining a swivel axis with a wedge-like member (i.e. portion extending into and bearing against 160) having a rounded tip) (Figures 1-4 and column 3, line 1 – column 7, line 18).

Mitchell discloses the claimed invention except for each wedge-like member being a wedge member having a pointed tip bearing against the joint section (i.e. pointed depression) in a way that allows tilting around the swivel axis. Angeli teach a joint (Figure 8B) comprising a wedge member (42) having a pointed tip (44, i.e. [www.merriam-webster.com](http://www.merriam-webster.com) defines a point as the terminal usually sharp or narrowly rounded part of something) bearing against a pointed joint section (43) that allows tilting around a swivel axis defined by the tip (column 2, lines 1-18). It would have been

obvious to a person having ordinary skill in the art at the time of the invention to construct the invention of Mitchell with the wedge member having a pointed tip bearing against a joint section that allows tilting around a swivel axis defined by the tip in view of Mitchell in order to allow for tilting around the swivel axis without generating significant friction.

Mitchell in view of Angeli disclose the claimed invention except for the wedge members being formed on the upper and lower joint elements and the pointed tips being provided on the central joint element. It would have been obvious to a person having ordinary skill in the art at the time of the invention to construct the invention of Mitchell in view of Angeli with the wedge members being formed on the upper and lower joint elements and the pointed tips being provided on the central joint element, since it has been held that a mere reversal of the essential working parts of a device involves only routine skill in the art. *In re Einstein*, 8 USPQ 167.

Mitchell in view of Angeli disclose the claimed invention except for the swivel axles being warped in relation to each other. It would have been obvious to a person having ordinary skill in that art at the time of the invention to construct the invention of Mitchell in view of Angeli with the swivel axles being warped in relation to each other, since the applicant has not disclosed that such is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of providing a warped swivel axle. *In re Dailey and Eilers*, 149 USPQ 47 (1966).

With regard to the statements of intended use and other functional statements, such as "for," they do not impose any structural limitations on the claims distinguishable over the invention of Mitchell which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from the prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

**Claims 8-13** are rejected under 35 U.S.C. 103(a) as being unpatentable over Mitchell (U.S. Patent No. 7,273,496) in view of Angeli (US Patent 5,593,447) further in view of Krueger et al. (U.S. Publication No. 2004/0143332).

Mitchell in view of Angeli disclose the claimed invention except for a means for keeping the ventral side areas at a fixed distance, and means for temporarily blocking mobility, where in the means is an insert with a lower end, an upper end, and a dovetail depression on the ventral sides where the insert can be inserted. Krueger et al. teaches an articulating implant a means (210) for keeping the two sections at a fixed distance and for blocking mobility and can be attached to the ventral side areas of the implant (100). More specifically, the means has an insert (218) that has an upper surface a lower surface, and the upper and lower sections of the implant (100) have a depression

(114) for receiving the implant. The insert can be dovetailed to match the depression (114) (Paragraph 130). Furthermore, the dovetail guides are tapered from the ventral side towards the dorsal side (Figure 42). It would have been obvious to a person having ordinary skill in that art at the time of the invention to construct the invention of Mitchell in view of Angeli with a dovetailed shape insert and a complimentary depression in the plates to block mobility and keep the implant at a fixed height in view of Krueger et al. in order to provide a stabilized insert form implanting into the intervertebral space.

**Claims 14-20** are rejected under 35 U.S.C. 103(a) as being unpatentable over Mitchell (U.S. Patent No. 7,273,496) in view of Angeli (US Patent 5,593,447) further in view of Michelson (U.S. Publication No. 2002/0052656).

Mitchell in view of Angeli disclose the claimed invention except for the upper and lower sections having two threaded drill holes running through the ventral side to the apposition surfaces with longitudinal axes forming an angle in the range between 20-65 degrees and diverge from the inner surfaces against the apposition surfaces.

Michelson teaches an intervertebral implant (800) having upper and lower members. Each member has two threaded holes passing from the interior of implant (800) through the apposition surfaces (Figures 42-46). With further reference to the figures, the holes form angles with the central axis and diverge from the inner surfaces against the apposition surfaces. It would have been obvious to a person having ordinary skill in the art at the time of the invention to construct the invention of Mitchell in view of Michelson with the upper and lower members having two threaded holes passing from the interior

of implant through the apposition surfaces at angles with the central axis diverging from the inner surfaces against the apposition surfaces in view of Michelson in order to rigidly secure the implant to the vertebral segment and also to pull each of the adjacent vertebral bodies toward the implant and towards each other (Paragraph 157).

Mitchell in view of Angeli disclose the claimed invention except for the central joint section comprising a first catching means and the lower joint section comprising a second catching means engaged with the first catching means. Michelson teach a first joint section (152) comprising a first catching means (156) and a second joint section (154) comprising a second catching means (i.e. the squared off opposing edges of 154) (Figure 1 and paragraph 0126). It would have been obvious to a person having ordinary skill in that art at the time of the invention to construct the invention of Mitchell in view of Angeli with the first joint section comprising a first catching means and the second joint section comprising a second catching means in view of Michelson in order to provide a secure releasable connection between the central and lower joint sections.

Mitchell in view of Angeli further in view of Michelson disclose the claimed invention except for the angle which the longitudinal axes of the holes makes with the central axis being in the range between 20-65 degrees. It would have been obvious to a person having ordinary skill in that art at the time of the invention to construct the holes at an angle between 20 and 65 degrees in relation to the central axis, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Mitchell in view of Angeli further in view of Michelson disclose the claimed invention except for the holes being conically tapered towards the apposition surfaces. It would have been obvious to a person having ordinary skill in that art at the time of the invention to construct the holes that are conically tapered towards the apposition surfaces, since the applicant has not disclosed that such is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of providing a conically tapered hole. *In re Dailey and Eilers*, 149 USPQ 47 (1966).

**Claim 21** is rejected under 35 U.S.C. 103(a) as being unpatentable over Mitchell (U.S. Patent No. 7,273,496) in view of Angeli (US Patent 5,593,447) further in view of Hedman et al. (US Patent 4,759,769).

Mitchell in view of Angeli disclose the claimed invention except for hinges being attached between the upper joint section and the central joint section through which the two joint sections are held together parallel to the central axis. Hedman et al. teaches two joint sections (42, 54 and 56) being held together (i.e. via 66) by a hinge formation (Figure 1 and column 2, line 44 - column 3, line 34). It would have been obvious to a person having ordinary skill in that art at the time of the invention to construct the invention of Mitchell in view of Angeli with the upper and central joint sections being held together by a hinge formation in view of Hedman et al in order to provide a secure and releasable attachment between the upper and central joint sections.

***Response to Arguments***

Applicant's arguments with respect to claims 1 and 4-21 have been considered but are moot in view of the new ground(s) of rejection.

In regards to the applicant's arguments with respect to the prior art used in the rejection mailed 05 August 2010, the examiner notes that these arguments are addressed by the new grounds of rejection as set forth above.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry E. Waggle, Jr whose telephone number is

(571)270-7110. The examiner can normally be reached on Monday through Thursday, 6:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas C. Barrett can be reached on (571)272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/L. E. W./  
Examiner, Art Unit 3775

/Thomas C. Barrett/  
Supervisory Patent Examiner, Art  
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